

REMARKS

This application is a national stage filing of PCT/KR03/000118, filed January 18, 2003. Claims 1-12 were pending as the result of a preliminary amendment submitted at the time of filing. In response to a restriction dated September 27, 2007, Applicants elected the claims of Group II (claims 1-5) without traverse. Claims 1-12, therefore, were pending with claims 6-12 withdrawn from consideration as being directed to a non-elected invention. Claims 1-5 are amended above and new claims 13 and 14 are presented. Claims 1-14 are now pending with claims 6-12 withdrawn from consideration as being directed to a non-elected invention.

Sequence Compliance

According to the Office Action, the present application is not in compliance with the sequence rules. Specifically, according to the Office Action, GRF analogs listed on pages 4 and 5 require a sequence identifier as do examples 1, 2 and 3.

A sequence listing for this application was submitted in both paper and computer readable forms when the application was originally filed. PAIR indicates that the sequence listing was received on July 15, 2005. The sequence listing contained two (2) sequences: each appearance of SEQ ID NO.: 1 and SEQ ID NO.: 2 throughout the specification represents an embodiment that has the amino acid sequence of SEQ ID NO.: 1 or 2 but differs with respect to protecting groups that are used during synthesis.

A substitute sequence listing is submitted herewith which is amended to include four additional sequences not previously identified in the listing and additional feature information regarding the existence of a disulfide bond in SEQ ID NO.: 1.

However, Applicant is not aware of any sequence rule that requires sequence information for named proteins, for example GRF analogs, where an amino acid sequence as defined by 37 C.F.R. § 1.821(a) is not part of the disclosure or for sequences that contain protecting groups present during synthesis of the peptide.

The sequence rules apply to applications in which an unbranched amino acid sequence of four or more residues is disclosed. Additionally, Table 6 in Appendix 2 of WIPO Standard ST.25 provides for information regarding additional features related to protein sequences including post-translational modifications of a residue, for example, amidation, formylation, phosphorylation etc. However, the rule does not appear to contemplate the addition of protecting groups during chemical synthesis, since no keys exist in Table 6 to describe such a feature.

Specification

The specification is amended above to include sequence identifiers and a substitute sequence listing. No new matter has been introduced by the amendments.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 1-5 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly, the claims are amended above.

Rejection Under 35 U.S.C. §103

Claims 1-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Alberecio in view of Kadereit et al., Barlos, Wilken, and/or Veronese.

The claims, as amended above, are directed to a method for the synthesis of a peptide that is particularly well suited to pegylation at selected sites. The method employs a specific protection/deprotection scheme that works successfully when used in conjunction with PEG conjugation to yield a peptide with PEG at selectively targeted sites.

Alberecio teaches the use of orthogonal protecting groups, in general. Kadereit et al., teach the use of acid-labile protecting groups for the synthesis of lipidated peptides including the use of trityl-based groups such as Mtt for lysine side-chain protection. Barlos teaches convergent protein synthesis, while Wilken provides an overview of protein synthesis. Veronese teaches the site-specific preparation of GRF-PEG conjugates by solution phase synthesis.

Though the cited references teach the use of several different protecting groups in peptide synthesis, the precise combination in the protection/deprotection strategy employed by Applicants is not taught or fairly suggested. Even though one of skill in the art might have been aware of various orthogonal protecting strategies, in the absence of empirical evidence, the particular combination claimed herein would not have given rise to an expectation of success in synthesizing a peptide amenable to site-specific PEG conjugation.

Withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

It is respectfully submitted that the above-identified application is now in condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,



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